AMENDMENTS

Applicant requests that the Examiner enter the following amendments:

IN THE CLAIMS:

Please amend the following claims:

1. (Currently amended) A method for detecting ~~one or more species of RNA that is epidermal growth factor RNA,~~ epidermal growth factor receptor RNA~~, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA~~ in ~~human~~ blood plasma from a human with colorectal cancer ~~or serum~~, the method comprising the steps of:

   a) centrifuging blood from a human with colorectal cancer to obtain plasma;

   b) extracting ~~total~~ extracellular total RNA from ~~human~~ blood plasma from a human with colorectal cancer ~~or serum~~, wherein a fraction of said extracted RNA comprises ~~one or more species of RNA that is epidermal growth factor RNA,~~ epidermal growth factor receptor RNA~~, her-2/neu RNA, c-myc RNA, or heterogeneous nuclear ribonucleoprotein A2/B1 RNA~~;

   c) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for ~~said~~ epidermal growth factor receptor RNA ~~species~~ or cDNA prepared therefrom, to produce an amplified product or using labeled primers or probes specific for ~~said~~ epidermal growth factor receptor RNA ~~species~~ or cDNA prepared therefrom to produce an amplified signal; and

   d) detecting either quantitatively or qualitatively the amplified product or amplified signal from said RNA or cDNA prepared therefrom.

2. (Cancelled)

3. (Currently amended) A method for hybridizing her-2/neu RNA from blood plasma or serum from a human with breast cancer, or cDNA produced therefrom, ~~using a probe that hybridizes with~~ the method comprising the step of hybridizing a primer or probe specific for her-2/neu RNA obtained from blood plasma or serum of a human with breast

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cancer,or by hybridizing a primer or probe specific for cDNA produced from her-2/neu RNA ~~therefrom~~ obtained from blood plasma or serum of a human with breast cancer.

4. (Cancelled)

5. (Withdrawn) A method for selecting a human or animal for an epidermal growth factor receptor-directed therapy, the method comprising the step of assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA, wherein the human or animal is selected for an epidermal growth factor receptor-directed therapy when said RNA or cDNA is detected by the assay.

6. (Withdrawn) A method according to claim 5 wherein the non-cellular fraction of a bodily fluid is blood plasma or serum.

7. (Withdrawn) The method of claim 5, wherein the therapy is a monoclonal antibody therapy.

8. (Withdrawn) A method for monitoring response in a human or animal to an epidermal growth factor receptor-directed therapy, the method comprising the step of assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA, wherein a response to said therapy is monitored by detecting said RNA or cDNA.

9. (Withdrawn) A method according to claim 8 wherein the non-cellular fraction of a bodily fluid is blood plasma or serum.

10. (Withdrawn) The method of claim 8, wherein the therapy is a monoclonal antibody therapy.

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11. (Currently amended) A method for evaluating a human having breast cancer for administering a her2/neu-directed therapy, the method comprising the step of assaying quantitatively or qualitatively blood plasma or serum from a ~~the~~ human for her-2/neu RNA, or cDNA prepared therefrom, wherein a her-2/neu directed therapy is administered to the human when her-2/neu RNA, or cDNA prepared therefrom, is detected in blood plasma or serum.

12. (Cancelled)

13. (Original) The method of claim 11, wherein the therapy is a monoclonal antibody therapy.

14. (Currently amended) A method for monitoring ~~response in~~ her-2/neu RNA in blood plasma or serum from a human with breast cancer [to] receiving a her2/neu-directed therapy, the method comprising the step of assaying quantitatively or qualitatively blood plasma or serum from ~~the~~ a human with breast cancer receiving a her-2/neu directed therapy for her2/neu RNA or cDNA prepared therefrom in a serial fashion, ~~wherein a response to said her2-neu-directed therapy is monitored by detecting said RNA or cDNA serially and detecting response to said therapy when a decreased amount of~~ whereby her-2/neu RNA in plasma or serum is ~~detected~~ monitored thereby.

15. (Cancelled)

16. (Original) The method of claim 14, wherein the therapy is a monoclonal antibody therapy.

17. (Withdrawn) A method for selecting a human or animal for a tyrosine kinase-directed therapy, the method comprising the step of assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA, wherein the human

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or animal is selected for a tyrosine kinase-directed therapy when said RNA or cDNA is detected by the assay.

18. (Withdrawn) A method according to claim 17 wherein the non-cellular fraction of a bodily fluid is blood plasma or serum.

19. (Withdrawn) The method of claim 17, wherein the therapy is a tyrosine kinase inhibitor, monoclonal antibody, small molecule, vaccine, or anti-sense therapy.

20. (Withdrawn) A method for monitoring response in a human or animal to a tyrosine kinase-directed therapy, the method comprising the step of assaying quantitatively or qualitatively a non-cellular fraction of a bodily fluid of the human or animal for epidermal growth factor receptor RNA or cDNA or epidermal growth factor RNA or cDNA, wherein a response to said tyrosine kinase-directed therapy is monitored by detecting said RNA or cDNA.

21. (Withdrawn) A method according to claim 20 wherein the non-cellular fraction of a bodily fluid is blood plasma or serum.

22. (Withdrawn) The method of claim 20, wherein the therapy is a tyrosine kinase inhibitor, monoclonal antibody, small molecule, vaccine, or anti-sense therapy.

23. (Withdrawn) A kit for selecting a human or animal for a therapy according to the method of claim 5, wherein said kit comprises primers or probes specific for said epidermal growth factor receptor RNA or epidermal growth factor RNA species.

24. (Withdrawn) A kit for monitoring tumor response in a human or animal according to the method of claim 8, wherein said kit comprises primers or probes specific for said epidermal growth factor receptor RNA or epidermal growth factor RNA species.

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25. (Withdrawn) A kit for selecting a human or animal for a therapy according to the method of claim 11, wherein said kit comprises primers or probes specific for said her2/neu RNA species.

26. (Withdrawn) A kit for monitoring tumor response in a human or animal according to the method of claim 14, wherein said kit comprises primers or probes specific for said her2/neu RNA species.

27. (Withdrawn) A kit for selecting a human or animal for a therapy according to the method of claim 17, wherein said kit comprises primers or probes specific for said tyrosine kinase RNA species.

28. (Withdrawn) A kit for monitoring tumor response in a human or animal according to the method of claim 20, wherein said kit comprises primers or probes specific for said tyrosine kinase RNA species.

29. (New) A method for detecting her-2/neu RNA in blood plasma from a human with breast cancer, the method comprising the steps of:

a) centrifuging blood from a human with breast cancer to obtain plasma;

b) extracting extracellular total RNA from the human's blood plasma, wherein a fraction of said extracted RNA comprises her-2/neu RNA;

c) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for her-2/neu RNA, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for her-2/neu RNA, or cDNA therefrom, to produce an amplified signal; and

d) detecting either quantitatively or qualitatively the amplified product or amplified signal of her-2/neu RNA, or cDNA therefrom.

30. (New) A method for detecting her-2/neu RNA in serum from a human with breast cancer, the method comprising the steps of:

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a) extracting extracellular total RNA from serum from a human with breast cancer, wherein a fraction of said extracted RNA comprises her-2/neu RNA;

b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for her-2/neu RNA, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for her-2/neu RNA, or cDNA therefrom, to produce an amplified signal; and

c) detecting either quantitatively or qualitatively the amplified product or amplified signal of her-2/neu RNA, or cDNA therefrom.

31. (New) A method for detecting epidermal growth factor receptor RNA in serum from a human with colorectal cancer, the method comprising the steps of:

a) extracting extracellular total RNA from serum from a human with colorectal cancer, wherein a fraction of said extracted RNA comprises epidermal growth factor receptor RNA;

b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for epidermal growth factor receptor RNA, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for epidermal growth factor receptor RNA, or cDNA therefrom, to produce an amplified signal; and

c) detecting either quantitatively or qualitatively the amplified product or amplified signal of epidermal growth factor receptor RNA, or cDNA therefrom.

32. (New) A method for evaluating a human having colorectal cancer for administering an epidermal growth factor receptor-directed therapy, the method comprising the step of assaying quantitatively or qualitatively blood plasma or serum from a human for epidermal growth factor receptor RNA or cDNA prepared therefrom, wherein the human is administered an epidermal growth factor receptor-directed therapy when epidermal growth factor receptor RNA or cDNA prepared therefrom is detected in blood plasma or serum from the human.

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33. (New) A method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in blood plasma from a human with lung cancer, the method comprising the steps of:

a) centrifuging blood from a human with lung cancer to obtain plasma;

b) extracting extracellular total RNA from blood plasma from said human with lung cancer, wherein a fraction of said extracted RNA comprises a heterogeneous nuclear ribonucleoprotein RNA species;

c) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for a heterogeneous nuclear ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for heterogeneous ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified signal; and

d) detecting either quantitatively or qualitatively the amplified product or amplified signal of heterogeneous ribonucleoprotein RNA, or cDNA therefrom.

34. (New) A method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in serum from a human with lung cancer, the method comprising the steps of:

a) extracting extracellular total RNA from serum from a human with lung cancer, wherein a fraction of said extracted RNA comprises a heterogeneous nuclear ribonucleoprotein RNA species;

b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for a heterogeneous nuclear ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for heterogenous ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified signal; and

c) detecting either quantitatively or qualitatively the amplified product or amplified signal of said heterogenous ribonucleoprotein RNA, or cDNA therefrom.

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35. (New) A method for detecting a heterogeneous nuclear ribonucleoprotein RNA species in pleural fluid from a human with lung cancer, the method comprising the steps of:

a) extracting extracellular total RNA from pleural fluid from a human with lung cancer, wherein a fraction of said extracted RNA comprises a heterogeneous nuclear ribonucleoprotein RNA species;

b) amplifying or signal amplifying said fraction of the extracted RNA or cDNA prepared therefrom, either qualitatively or quantitatively, using primers or probes specific for a heterogeneous nuclear ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified product or using labeled primers or probes specific for heterogeneous ribonucleoprotein RNA species, or cDNA therefrom, to produce an amplified signal; and

c) detecting either quantitatively or qualitatively the amplified product or amplified signal of said heterogeneous ribonucleoprotein RNA, or cDNA therefrom.

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